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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/815,084 | 03/31/2004 | Stephen T. Flock | D6462CIP2 | 7354 |
| 7590 | 12/31/2008 | | EXAMINER | |
| Benjamin Aaron Adler ADLER & ASSOCIATES 8011 Candle Lane Houston, TX 77071 | | | ROANE, AARON F | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3769 | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 12/31/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/815,084 | FLOCK ET AL. | |
| | Examiner | Art Unit | |
| | Aaron Roane | 3769 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 29 September 2008.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-9, 11, 13 and 15-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-9, 11, 13 and 15-24 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 21 June 2004 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) Notice of Informal Patent Application
 6) Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 13 and 15-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Gordon (U.S. Patent 4,889,120).

Regarding claims 1-5, Gordon discloses a method of treatment for one or more tissue substrates in an individual, comprising: securing the tissue substrates proximal to a ferromagnetic metal susceptor; applying radiofrequency energy that generates a magnetic field to said substrate(s) or to said susceptor or to a combination thereof to inductively generate heat therein; and affixing said substrates together via said heat thereby effecting treatment, see abstract, col. 2:28 - col. 3:62.

Regarding claims 6 and 7, Gordon discloses the substrates may be further secured by a surgical fastener in the form of 2 to 3 sutures, see col. 6:29-31.

Regarding claims 8 and 9, Gordon discloses the claimed invention, see col. 3:8-25 and col. 6:43-48 and claims 1-4, particularly claim 4.

Regarding claims 13, 15-18, Gordon discloses the claimed invention, see col. 5:48-65.

Regarding claims 19 and 20, Gordon discloses the claimed invention, see col. 2:1-18 and col. 2:44-53.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon (U.S. Patent 4,889,120) as applied to claim 1 above, and in view of Aida et al. (U.S. Patent 5,897,495).

Regarding claim 11, Gordon discloses the claimed invention except for explicitly reciting the radio frequency energy is applied in pulses. It is well known in the art that radio frequency may be applied in a continuous duration or in discreet pulses. Aida et al.

disclose a system and method of heat-treating tissue and teach “a transmitter coil for transmitting radio frequency pulses to the treatment target portion such that the thermal treatment can be applied to the treatment target portion by the heat induced by the radio frequency pulses,” see col. 12:56-60 and figure 9. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Gordon, as taught by Aida et al., to provide radio frequency energy in pulses in order to heat-treat tissue.

Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon (U.S. Patent 4,889,120) as applied to claim 1 above, and further in view of Sawyer (U.S. Patent 5,824,015) in further view of Hedge et al. (U.S. Patent 6,656,174).

Regarding claims 21 and 22, Gordon discloses the claimed invention except for explicitly reciting controlling the affixing of said substrates via feedback monitoring of a property of said susceptor, said energy or a combination thereof, wherein said property is heat, an electrical property, eddy currents, conductivity, or frequency changes or a combination thereof. It is well known in the art that the connection of different portion of biological tissue can be effected by the crosslinking of collagen, wherein two portions of biological tissue are placed in abutment with each other and heated by various means: laser, RF, microwave, resistive heating, etc. (well known in the art) in order to achieve the crosslinking. It is important that the heating (i.e. temperature obtained by tissue) be high enough to achieve the crosslinking but not so high as to damage and/or ablate the tissue. Sawyer discloses a method for welding biological tissue and teaches that it is well known

in the art to denature of collagen containing substances and/or tissues (interpreted as including crosslinking collagen) by heating the substances and/or tissues to a temperature of 45° C to 75° C in order to form tissue welds/seals, see col. 2:27 – col. 3:25 in general and col. 3:46-65 in particular. Hedge et al. disclose and device and method for heat treating biological tissue with RF energy and teach “the interior electrodes 48 and temperature sensing elements 26 are electrically coupled to the respective RF generator 18 and controller 19, allowing RF power to be delivered to the inflatable chambers 36, and thus, the targeted tissue, under temperature-feedback control,” see col. 8:65 – col. 9:2 and figures 1 and 5. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Gordon, as taught by Sawyer, to provide a particular heating temperature range for the treated tissue site in order to achieve a collagen crosslinked tissue seal/weld, and as further taught by Hedge et al., to provide the system with temperature sensors and temperature-feedback control in order to obtain and maintain a particular tissue treatment site temperature (tissue/substrate heat).

Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon (U.S. Patent 4,889,120) in view of Sawyer (U.S. Patent 5,824,015) and in further view of Hedge et al. (U.S. Patent 6,656,174) as applied to claim 22 above, and still in further in view of Eggers et al. (U.S. Patent 5,366,443).

Regarding claims 23 and 24, Gordon in view of Sawyer in further view of Hedge et al. disclose the claimed invention except for heat is monitored via infrared optical detection. It is extremely well known in the art to provide temperature sensors in various

alternate/equivalent means such thermistors and infrared optical sensors for example. Eggers et al. disclose a medical device and method and teach “the temperature sensing may be achieved using fiber optics with infrared sensing technique, a thermocouple, a thermistor or other temperature sensing means,” see col. 11:34-42. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Gordon in view of Sawyer in further view of Hedge et al., as taught by Eggers et al., to provide the device and system with fiber optics with infrared sensing technique (optical infrared sensing) in order to provide specific example of temperature sensing means.

Response to Arguments

Applicant's arguments filed 7/8/2008 have been fully considered but they are not persuasive. The examiner will address each argument/remark in turn.

On page 6, last paragraph, Applicant asserts “Gordon does not teach the method of treatment of one or more substrates in an individual, comprising securing said substrate(s) proximal to a susceptor, wherein said substrate is intact, and applying radiofrequency energy.” The examiner strongly disagrees as Gordon clearly discloses the susceptors are introduced into the substrate(s) (biological structure(s)) by passive means or by injection, see col. 2:13-18; “the minute particles are to be injected or absorbed into the edges of the biological structures through the use of any suitable compatible liquid or solid vehicles,” see col. 5:13-15; and further that the introduction of the “particles are either intracellular and/or extracellular and can be introduced at

the time of connection and/or prior to connection,” see abstract. Additionally, Gordon discloses “an adhesive may be used which is applied with the particles and which is cured or activated by heating of the particles,” see col. 6:43-48. Clearly the susceptors are secured to the substrate (tissue, biological structures). As far as the substrates being intact, the sealing/fusing of blood vessels disclosed by Gordon clearly provides an example of two substrates (blood vessels) that are intact, the fact that the blood vessels are separate structures that are surgically connected to form a single structure does not preclude them from being “intact.” As far as the RF energy, Gordon discloses the use an electromagnetic alternating frequency between 1 Hz and 10 MHz in order to heat the susceptors, see col. 5:66-68.

Next in the same passage, Applicant asserts “Gordon does not teach the method where said substrate is an implant or a bandage, or it is secured by a surgical fastener, a laminate or a surgical fitting, or by an adherend. The examiner strongly disagrees as Gordon discloses “an adhesive may be used which is applied with the particles and which is cured or activated by heating of the particles,” see col. 6:43-48. Regarding Applicants assertion that Gordon does not disclose the adherend is a polymer or protein, in the rejection to claims 8 and 9, the examiner cites col. 3:8-25 and col. 6:43-48 and claims 1-4, particularly claim 4, wherein col. 3:8-25 and claim 4 discloses a susceptor comprising “iron-sulfur proteins such as ferredoxin and rubredoxin,” while col. 6:43-48 simply discloses an adhesive. The claim simply requires an adherend (“something bound to”) comprising a protein, and since col. 3:8-25 and claims 1-4 disclose a susceptor comprising (meaning “having at least this, but maybe more”) an iron sulfur protein, both claims 8 and 9 are anticipated. Additionally, Gordon clearly discloses the substrates are secured by a surgical fastener in the form of 2 to 3 sutures, see col. 6:29-31.

Applicant should be aware that the rejections of claims 11 and 21-24 are based on a new grounds of rejection (Gordon in view of newly cited prior art), however the provision of temperature feedback control for systems that provide tissue heat-treatment is very well known as are infrared optical sensors.

The rejections based in part or whole on the U.S. Patent to Paulus et al. have been withdrawn due to Applicant's amendments.

This action is made non final.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. When responding to this Office action, Applicant may wish to review the following U.S. Patents: 6,458,109 to Henley et al. and 6,350,274 to Li.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 8:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron Roane/
Examiner, Art Unit 3769

/Henry M. Johnson, III/
Supervisory Patent Examiner, Art Unit
3769